REMARKS/ARGUMENTS

Claims 1 to 31 are pending in the present patent application. In view of the following remarks, reconsideration and withdrawal of the rejections are respectfully requested.

Discussion of the Obviousness-Type Double Patenting Rejections

Claims 1 to 31 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1 to 31 of commonly owned U.S. Patent Application No. 11/639,172 and claims 1 to 31 of commonly owned U.S. Patent Application No. 10/231,438. Applicant requests that this rejection be deferred pending some identification of allowable subject matter, at which time applicant will consider the filing of a suitable terminal disclaimer.

Discussion of the Rejection under 35 U.S.C. § 102(b)

Claims 1 to 31 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by PCT Publication No. WO99/11605 to Fujimoto et al. ("Fujimoto"). Applicant respectfully traverses this rejection because Fujimoto does not disclose each and every element of Applicant's claimed inventions.

For a reference to anticipate a claim under 35 U.S.C. § 102, "the identical invention must be shown in as complete detail as is contained in the ... claim" (*Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989)). Further, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" (*Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic (*In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)). In particular, the examiner must provide a basis in fact and/or technical reasoning to reasonably support a determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art (*Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)).

Applicant's claims define a solid pharmaceutical composition for treating a cyclooxygenase-2-disorder disorder or condition comprising between about 200 and about 400 mg of 5- methyl-2- (2'-chloro-6'-fluoroanilino) phenylacetic acid, wherein the residual moisture level of said composition is between about 1.5% and about 5% (see, e.g. claim 1). Applicant's claims also define a method for stabilizing 5-methyl-2- (2'-chloro-6'- fluoroanilino) phenylacetic acid in a solid pharmaceutical composition, comprising producing a solid pharmaceutical composition comprising 5-methyl-2- (2'-chloro-6'- fluoroanilino) phenylacetic acid wherein said composition has a residual moisture level between about 1.5% and about 5% (see, e.g. claim 12). Further, applicant's claims define a dried granulation comprising 5-methyl-2- (2'-chloro-6'-

fluoroanilino) phenylacetic acid, microcrystalline cellulose, lactose monohydrate, cross-carmellose sodium, wherein the residual moisture level of said granulation is between about 2.5% and about 4.5% (see, e.g. claim 21).

In contrast, Fujimoto teaches pharmaceutical compositions comprising 5-alkyl-2-arylaminophenylacetic acids with "suitable" excipients or carriers (*see* page 18, paragraph 8, page 19, and page 20, paragraphs 1 to 5). Fujimoto at least does not teach any residual moisture level of the compositions therein. In fact, Fujimoto does not teach or exemplify any specific formulations for pharmaceutical compositions. Although compositions within the scope of Fujimoto might be prepared with the recited residual moisture levels, such residual moisture levels are not a characteristic that necessarily flows from the teachings of Fujimoto. As such, the Action provided no basis to reasonably support any determination that the recited residual moisture levels of applicant's claimed inventions are an inherent characteristic of Fujimoto. Applicants respectfully submit that the present claims are thus patentable over Fujimoto at least for the above reason.

Discussion of the Rejections under 35 U.S.C. § 103(a)

Claims 1 to 31 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Fujimoto in view of U.S. Patent No. 6,063,811 to Hancock et al. ("Hancock"). Applicant respectfully traverses this rejection as the combination of Fujimoto and Hancock does not produce any composition, method or granulation of the presently claimed invention.

"A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field" (*In re Kotzab*, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000)). "The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time" (*In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) (quoting *Interconnect Planning Corp. v. Feil*, 227 U.S.P.Q. 543, 547 (Fed. Cir. 1985)). To establish a *prima facie* case of obviousness, the examiner must show reasons that the skilled artisan, with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed (*see In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998)).

As detailed above, applicant's claimed inventions recite residual moisture levels of between about 1.5% and about 5% (*see* claim 1 and 12) or between about 2.5% and about 4.5% (*see* claim 21). Fujimoto, in contrast, does not expressly or inherently teach or suggest any particular residual moisture level. Hancock, like Fujimoto, also contains no teaching or suggestion of any particular residual moisture level in the compositions disclosed therein. As both Fujimoto and Hancock lack any disclosure regarding residual moisture levels, the combination of Fujimoto and Hancock cannot produce any composition, method or granulation

of the presently claimed invention. Reconsideration and withdrawal of the rejection are requested respectfully for at least this reason.

Conclusion

Applicant believes that the foregoing constitutes a complete and full response to the Action of record. If there are any issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney.

It is hereby requested that the term to respond to the Action of July 16, 2007 be extended pursuant to 37 C.F.R. § 1.136(a) for three (3) months, from October 16, 2007 to January 16, 2007. The Commissioner is hereby authorized to charge any fees required to Deposit Account No. **19-0134** in the name of Novartis.

Respectfully submitted,

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